

SETTING

METHYL BROMIDE
TARGET EXPOSURE LEVELS

SEPTEMBER 2003

HOW METHYL
BROMIDE
TARGET
EXPOSURE
LEVELS ARE
DETERMINED

California's methyl bromide regulations, being revised now by the California Department of Pesticide Regulation (DPR), are designed to ensure that people are protected from unsafe methyl bromide air levels. Extensive air monitoring around methyl bromide applications has not shown any imminent health hazard to communities. However, being health protective means enhancing existing controls to ensure that workers and others who may face ongoing exposure to methyl bromide do not suffer ill effects.

The control measures in the regulations are based on extensive review and evaluation of hundreds of scientific studies. To understand the scientific basis of the regulations, it is helpful to have some background.

The goal of the first set of methyl bromide regulations, adopted in 2001, was to protect against *short-term* (one-day) exposure. Those control measures were designed to achieve a target exposure level of 210 parts per billion (ppb), averaged over a 24-hour period.

Generally, target exposure levels must be lower when the period of exposure is longer. DPR health evaluation scientists recommend target exposure levels (also called *reference concentrations*) of 16 ppb for adults and 9 ppb for children for subchronic "seasonal" exposures of several weeks. We also determined that long-term (lifetime) exposures should not exceed 1 ppb. These target levels were considered to be protective of children and sensitive populations.

So our next step is to ensure protection against potential health effects from *longer-term* or subchronic (four- to eight-week) exposures, and this is the goal of this new round of regulations.

HOW DOES DPR SET TARGET EXPOSURE LEVELS?

EXPOSURE
DURATIONS

- **Acute:**
Short-term, over a day or so
- **Subchronic:**
Seasonal, over several weeks or months
- **Chronic:**
More than a year, or lifetime

When DPR health evaluation scientists develop their recommendations, their goal is to identify exposure levels that will not cause health problems. They do this through a process called risk assessment, which is designed to answer questions about how toxic a chemical is, what exposure results from its various uses, what is the probability that use will cause harm, and how to characterize the risk. (See DPR's fact sheet, *Assessing the Health Risk of Pesticides* for more information on this process.)

DPR managers use the recommendations of the scientists to make decisions about how to

control the use of a chemical. At specific concentrations, essentially all substances are associated with some degree of risk. However, there are levels of chemical exposure that are too small to be of health concern. DPR's goal is to reduce the exposure to that level. We take into account not only risk information but information on how the pesticide is used, as well as recommendations from other DPR staff on how enforceable and practical any control measures will be. This is a qualitative process (rather than quantitative), but the guiding principle is that DPR will not allow a chemical to be used unless it can be used safely.

HOW WERE THE METHYL BROMIDE TARGET EXPOSURE LEVELS DEVELOPED?

To develop a target level for *subchronic exposure*, DPR scientists went through a rigorous and exacting review and evaluation process. A provisional estimated reference concentration of 1 to 2 ppb was developed in 2001, based on incomplete data. That same year, DPR mandated the methyl bromide industry to do additional air monitoring. The industry also responded to a National Academy of Sciences recommendation and conducted an additional toxicology study designed to better gauge the neurological effects of methyl bromide following subchronic exposures.

With these and other studies, DPR scientists now had the data to more accurately characterize methyl bromide risks and develop more effective protections against longer-term exposures. In February 2003, the Department held a public workshop to present staff analysis and solicit public comments on an appropriate target exposure level for subchronic exposures. The work of DPR's health evaluation scientists has been peer-reviewed by the National

Academy of Sciences, the U.S. Environmental Protection Agency (U.S. EPA), and the University of California, who have all agreed that the approach being taken by DPR is scientifically sound and valid.

The regulations DPR implemented in 2001 were designed to achieve a target exposure level of 210 parts per billion (ppb), averaged over a 24-hour period, to protect against short-term exposure. However, to protect against possible health effects from subchronic exposure, DPR health evaluation scientists recommended the reference concentrations of 16 ppb for adults, and 9 ppb for children.

In recommending these levels, our scientists assumed that subchronic exposure is continuous over a one-month period. For exposure periods beyond one month, they assumed that the exposures would be intermittent rather than continuous. These target levels provide an adequate margin of safety for human subchronic exposure to methyl bromide.

WHAT IS THE RELATIONSHIP BETWEEN THE TARGET LEVELS AND THE USE RESTRICTIONS?

DPR environmental scientists used these reference concentrations to develop new protective use restrictions. They did this by comparing the target concentrations to the air monitoring data, using computer models to estimate methyl bromide emissions under a variety of use patterns.

The reference concentrations set out in DPR's risk assessment are based on the assumption that exposure is *averaged* over a given period — one day, several weeks, or months, with less exposure allowed as

the period of exposure lengthens. Exposure may be higher or lower at any point, as long as it averages at or below the reference concentration.

Whether these reference concentrations are for short-term or longer-term exposure, they incorporate a 100-fold margin of safety, that is, the target exposure level is set 100 times lower than a level that caused no health effects in animal studies. The 100-fold factor is designed to take into account the fact that some people are

The 2001 regulations were designed to protect against *short-term* exposure. The new regulations were developed to protect against *seasonal* exposures to methyl bromide.

RELATIONSHIP OF TARGET LEVELS AND RESTRICTIONS (CONTINUED)

(Continued from page 2)

more sensitive to health effects than others, and also assumes that people are more sensitive than experimental animals to the effects of methyl bromide. This margin of exposure means that even if people are exposed at the reference concentrations,

we would not anticipate health effects to occur. Even exposures slightly above the target level should not pose a health concern. Should this occur, DPR would take necessary steps to reach our desired level of protection.

HOW CERTAIN ARE YOU OF YOUR CONCLUSIONS?

There is always a degree of scientific uncertainty in risk assessments. In fact, in acknowledgement of this uncertainty, our risk estimates err on the side of safety. We can never be absolutely sure of the exact levels of a chemical that are present in the environment on any given day, at any given place. We also know that there are variations between how people react to exposure, that some people are more susceptible than others.

To account for these uncertainties and to acknowledge gaps in science, we build factors into our risk estimates which tend to overestimate what we believe to be the actual risk. Where there is uncertainty, or where our information is less complete than we would like, we make assumptions that tend to overestimate the risk as a way to protect public health.

This is done to ensure that health will still be protected should new science be developed that shows that some of our assumptions or policies were not correct.

An example of a health-protective assumption we make is in interpreting the results of animal studies for cancer. When animals get cancer from very large doses of a chemical given in laboratory experiments, DPR assumes that people may get cancer

from that chemical even at the much lower levels typically found in our environment.

We make this assumption so that any errors in judgment we make are on the side of safety. This also means that the risk we estimate may be a lot lower, should one or more of our assumptions prove to be overprotective. DPR routinely takes these precautions to ensure that the public's health and safety are protected.

Although extensive information exists to evaluate the reference concentrations for methyl bromide, some of the data can lead to differing opinions in the scientific community. Differing scientific opinions are commonplace in determining risk. That is the main reason for subjecting risk assessments to review by other scientific experts in the field.

The methyl bromide risk assessment was peer-reviewed by the National Research Council as well as other state and federal agencies and external experts. All of these reviewers add to the weight of evidence that DPR scientists and risk managers consider.

In developing our regulations, our goal has been to ensure that short term (acute) exposures do not exceed 210 ppb, seasonal (subchronic) exposures do not

Exposure may be higher or lower at any given point in time, as long as it averages at or below the reference concentration.

(Continued on page 4)

HOW CERTAIN ARE YOU OF YOUR CONCLUSIONS? (CONTINUED)

(Continued from page 3)

exceed 16 ppb for adults, and 9 ppb for children, and long term (lifetime) exposures do not exceed 1 ppb. The lifetime reference concentration has the most consensus among the scientific community, with Cal/EPA's Office of Environmental Health

Hazard Assessment and U.S. EPA reaching the same conclusion as DPR. On the other hand, the target levels for short-term and seasonal exposures have been the subject of differing opinions.

HOW WAS THE SEASONAL REFERENCE CONCENTRATION FOR METHYL BROMIDE DEVELOPED?

To develop a target level for seasonal exposure, DPR scientists reviewed more than 100 methyl bromide studies. In 2001, to complete their risk assessment, these scientists developed a provisional target level of 1 to 2 ppb. However, a key toxicology study on which this estimate was based was considered inconclusive, because of the equivocal and subjective nature of the findings.

The result was an estimated reference concentration for *subchronic* exposure that was identical to the well established reference concentration for lifetime exposure. Given this anomaly, DPR asked the National Academy of Sciences National Research Council (NRC) specifically to review the provisional subchronic reference concentration. The NRC echoed the reservations of DPR scientists about the toxicology study on which the provisional estimate was based. Among other recommendations, the NRC suggested a new study be conducted.

A new study was submitted late last year, and was peer-reviewed by a member of the NRC panel, by two expert toxicologists from the University of California, and by U.S. EPA. These reviewers agreed the new study provides more conclusive support for calculating subchronic target exposure levels for methyl bromide. DPR scientists evaluated this study in the context of the many volumes of other data and concluded that exposure levels of up to 9 ppb for children and 16 ppb for adults would be health protective for subchronic exposures. While scientists often differ on their conclusions, DPR's risk assessment is supported by the assessments of the peer reviewers.

DPR risk managers used the reference concentrations recommended by the scientists to develop use restrictions designed to protect public and worker health from potential adverse effects of methyl bromide.

DPR has the nation's strictest controls on methyl bromide use. The new regulations will enhance these protections.

ABOUT THE DEPARTMENT OF PESTICIDE REGULATION

The California Department of Pesticide Regulation (DPR) protects human health and the environment by regulating pesticide sales and use and by fostering reduced-risk pest management. DPR's strict oversight includes product evaluation and registration, environmental monitoring, residue testing of fresh produce, and local use enforcement through the county agricultural commissioners. DPR is one of six boards and departments within the California Environmental Protection Agency.

